TESTIMONY

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Hearing of the United States Senate Cancer Coalition

National Cancer Legislative Advisory Committee Report
Conquering Cancer: A National Battle Plan to Eradicate Cancer in Our Lifetime

October 10, 2001

The Honorable Dianne Feinstein
The Honorable Sam Brownback
Co-Chairs

Testimony Before the Senate Cancer Coalition
Dr. Anna D. Barker
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Senators Feinstein and Brownback, I very much appreciate the opportunity to appear before the Senate Cancer Coalition today on behalf of the National Cancer Legislation Advisory Committee (NCLAC), and the large number of individuals from the academic, public and private sectors who contributed both directly and indirectly to the NCLAC Report, "Conquering Cancer: A National Battle Plan to Eradicate Cancer in our Lifetime". I am specifically speaking on behalf of several of my colleagues who worked to consolidate and prioritize the recommendations for "translational research", including Dr. Ron Herberman, Dr. Albert Einstein and Mr. Carl Dixon.

Senator Feinstein, thank-you for your leadership and vision and your commitment to end the human and economic devastation caused by cancer. Senator Brownback, thank-you for joining us in taking the bold steps needed to conquer this tragic disease that will take the lives of over 560,000 Americans this year.

I am Dr. Anna D. Barker, President and CEO of BIO-NOVA, a biotechnology development company in Oregon, and a member of the NCLAC Committee. In addition to being a scientist and biotechnology entrepreneur, I am a passionate advocate for a reinvigorated, unified national effort to prevent and cure cancer and I believe that we must act with a real sense of urgency. We can do this, and we must – for the price of not acting is far too high.

Cancer is the disease that Americans fear most, and their fears are understandable. As we look forward into this new century, at current rates, it is projected that one-half of men and one-third of women in America today will be diagnosed with cancer in their lifetime, and twenty-five percent of our population will die from cancer. Since 1990, there have been 12 million new cases of cancer diagnosed and 5 million Americans have died from their disease**.** Although cancer is already an epidemic in America, unless we act, it will likely become a major healthcare crisis as the "baby boomers" age and our demographics change over the next 10-20 years. These daunting statistics inspired NCLAC members and contributors alike to identify the key resources, public policies, partnerships and tools needed to accelerate progress toward our unified goal to prevent and cure cancer.

Fortunately, our past investments are paying off in an ever-increasing understanding of the fundamental differences between cancer and normal cells. Due to an unimagined array of opportunities across the continuum of cancer research, we can now envision a future where we will cure more cancer patients, treat cancer as a chronic illness, and develop rational and effective cancer prevention strategies.

Completing the sequencing of the human genome and advances in complementary areas of biomedical research such as immunology, biochemistry and informatics over the past 25 years provide us with a solid foundation for future progress. For example, progress in

areas such as genomics and proteomics offer new and novel pathways to discover, develop and commercialize targeted, non-toxic agents and rational technologies to prevent and cure cancer. However, as you have heard from my colleagues, although we have made great strides in understanding the complexities of the cancer cell, it is a "work in progress". There is a great deal left to discover. Therefore, we must strengthen our commitment and redouble our support of the basic research required to "fuel" the engine of discovery that will drive the development of the new medicines and technologies needed to conquer cancer.

Today, I want to direct your attention to the "continuum" that we refer to as medical/cancer research. In fact, the vital basic research conducted by individuals and groups of scientists in the public, academic and private sectors is just the beginning of the story. Idea-driven basic research is the resource for discovery. Selective laboratory advances, or discoveries, may represent the genesis of new (potentially more effective) drugs and technologies to prevent and treat cancer and/or improve quality of life for cancer patients. Advancing these "discoveries" through the myriad of preclinical, clinical and regulatory steps required to become the new commercial products so badly needed to address the current and future cancer epidemic is called "translational research", or simply "translation".

For the purposes of our discussion, "translation" is defined as "the laboratory and clinical research and testing needed to transform scientific discoveries into new approaches and products that can prevent, control, diagnose and treat cancer, optimize quality of life and ultimately, cure cancer." The "continuum" of cancer research begins with basic research and proceeds through discovery, preclinical development, clinical development, regulatory review, approval and finally, commercialization of a new medicine or device. This process involves vital links between the public (research), academic and private and regulatory sectors. Our ability to capitalize on our past and future investments in biomedical research for the benefit of cancer patients, and indeed all of our citizens, will depend in large measure on our ability to build the needed "infrastructure" to support translational research.

Thus, although we are poised to make real progress toward realizing our vision of preventing and curing cancer, the members of NCLAC, and our collaborators, recognized that there are major barriers to overcome to optimally leverage the considerable capabilities of all involved sectors. In short, we must create the needed national infrastructure and systems required for the "seamless" transfer of technology, and the subsequent development of new products, to prevent and cure cancer. As detailed in the NCLAC report this will involve creating "centers" to conduct this research, training critically needed personnel, increasing participation in clinical trials, creating more effective public private partnerships, building our national bio-informatics capabilities and updating and reforming the regulatory process.

In developing its Goals and Recommendations for "translation", the members of the NCLAC held far-ranging discussions within the Committee and sought input from experts representing academic medical centers, pharmaceutical, biotechnology and device

companies and federal agencies. Optimizing the critical and distinct roles of each of these sectors, reducing unnecessary duplication and building new systems to increase both the efficiency and effectiveness of translation, and ultimately the commercialization of new "cancer products" represents a major challenge. Although there are a number of barriers to be addressed, the NCLAC attempted to prioritize its recommended goals and specific actions to focus on areas that are most likely to benefit from national legislation. The goals delineated in Chapter 2 of the NCLAC Report, "Translating Scientific Discoveries Into New Cancer Medicines and Technologies," include the following:

- **Enhance our cancer research centers (and other cancer focused efforts) to build a multidisciplinary network of "translational centers" to move new drugs and technologies forward into clinical trials, and ultimately develop new methods and products to prevent and cure cancer.**

- **Streamline and accelerate the Food and Drug Administration's (FDA) approval system for cancer drugs, biologics, devices and technologies.**

- **Empower federal agencies to build public-private partnerships across the entire continuum of cancer research to ultimately develop new cancer treatments, preventives and technologies.**

As outlined in the Report, the achievement of each of these Goals is supported by a series of specific recommendations for action. I will not reiterate these recommendations, but rather offer the overall thinking and ultimate rationale that prompted us to set these Goals and develop the recommended strategies for achievement.

Translational Cancer Research Centers - The nation's cancer centers (and other community based cancer efforts) represent an enormous asset and an underutilized resource for translational research. National Cancer Institute (NCI) designated centers (and associated academic and other medical centers) represent a logical focus for convergence of the multiple disciplines and technologies needed to translate laboratory discoveries into preclinical and early clinical development to set the stage for seamless technology transfer to the private sector. These centers will face new challenges, especially the development of a new culture that will facilitate and encourage multi-disciplinary, team-focused, translational research. We must empower the NCI to make the needed investments, and take the necessary actions required, to bring together the personnel, facilities, equipment and support mechanisms required to develop a network of "translational cancer research centers". In parallel, the NCI must also utilize these centers to expand and enhance the nation's capacity to conduct cancer clinical trials; and to develop the public-private partnerships needed to fully leverage the strengths of both sectors.

Streamlining/Accelerating FDA Review and Approval – Regulatory review and approval represents a rate-limiting step in the development and commercialization of any new drug, device or technology to prevent, detect, or treat cancer and manage its symptoms. The members of the NCLAC, with extensive input from academic, private

and public sector experts, concluded that the Food and Drug Administration (FDA) must become a more interactive partner with all sectors involved in the research, development and commercialization of new cancer products. The Agency must also increasingly utilize contemporary science to streamline the approval of new oncology drugs and devices. To optimize the fruits of basic and translational research and provide increased numbers of more effective products to prevent and treat cancer will require that the FDA increasingly develop review and approval criteria that treat oncology drugs and devices in a unique manner. To this end, NCLAC recommends that FDA centralize all of the processes and activities that pertain to the review and approval of new cancer drugs and devices that are intended for the prevention, detection and treatment of cancer.

Building Public Private Partnerships – Increasing the active and meaningful participation of the private sector is crucial to winning the "war" on cancer. To ensure that the private sector becomes a full partner in the national cancer program will require that the NCI and other federal agencies be charged with the responsibility, and given the required authorities, to develop responsive public-private partnerships. Moreover, the market and regulatory risks to private companies represented by cancer require that we explore the development of realistic incentives (Orphan Drug Act, selective market exclusivity, etc.) to encourage their role as an active partner in any reinvigorated national effort to finally defeat cancer. Specifically, areas of critical need such as cancer prevention and informatics represent significant challenges in terms of engaging the private sector, and should receive immediate attention.

Closing Comment - The tragic events of September 11, 2001 were devastating, but Americans have emerged united in our resolve to defeat terrorism and defend our way of life. I believe that this strength and resolve can also be channeled into ensuring the future health of our nation by eliminating the specter of cancer. Cancer affects every family in America, including my own. I have lost many family members and loved ones to cancer, including my sister and mother to breast cancer, but I know that my story is repeated every day across America. We are all left with a deep sense of loss and a will to do more. The NCLAC Report represents an opportunity to increase progress against cancer by harnessing the strengths of the respective sectors involved in the continuum of cancer research and product commercialization and delivery for the benefit of all of our citizens. Senators, it is time to turn the pain of those living with cancer and those who have lost their battle(s) into action(s) to reduce or remove the shadow of cancer from our lives and from the lives of future generations.

I will be happy to answer any questions. Thank-you.